K140644

JUN 19 2014

510(k) Summary
ProCem™ Otologic Bone Cement

Date Prepared: 5 March, 2014

Submitter: Ototronix LLC
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Proprietary Name: ProCem™ Otologic Bone Cement

Common/Usual Name: Cement, Ear, Nose and Throat

Classification Name: Classification Status: Class II per regulations 872.3275
Product Code: NEA

Establishment Registration Number: 3008612563

Description:
ProCem™ is glass ionomer cement that is provided as two components, a glass powder and polyacrylic acid liquid. By mixing the two components, viscous moldable ionomeric cement is obtained which hardens in situ.

ProCem™ is provided in a sterile capsule. The capsule includes the two separate components, a glass powder and polyacrylic acid liquid. An activator is used to release the liquid component prior to use. The capsule is then placed in a mixer, which mixes the glass powder and polyacrylic acid liquid to form a compliant cement. The applicator is used to apply the compliant cement to the appropriate location in the middle ear. The cement then hardens in place to provide a permanent bond.

Indications for Use:
ProCem™ is intended for non-weight bearing applications in Otologic surgery, such as:

1. Reconstruction of ossicular bones or mechanical coupling of the ossicular chain.
2. Mechanical stabilization of middle ear and cochlear implants.
3. Attachment of middle ear implants to the ossicular bones.

Substantial Equivalence:
Ototronix believes that ProCem™ is substantially equivalent to the following devices:

- SerenoCem, K003567
- EnvoyCem, K080032

ProCem™ is a glass ionomer cement as is EnvoyCem and SerenoCem and has essentially the same intended use as the predicate devices.

Technological Characteristics:
Like the predicate devices, ProCem™ is intended for use in various otologic surgical applications. ProCem™ is glass ionomer cement (GIC) as is EnvoyCem and SerenoCem. GIC has a long history of use in otologic surgery applications. GIC is provided sterile as two components that require mixing prior to use. The ProCem™ capsule components and accessory devices (activator, mixer, applicator) are identical to those of the predicate devices.

Biocompatibility:
The ProCem™ Otologic Bone Cement and the predicates are categorized as implantable devices for tissue/bone contact with permanent duration (>30 days) in accordance with ISO 10993-1 *Biological Evaluation of Medical Devices*. The GIC cements have a long history of safe and effective use in otologic surgery applications and have demonstrated compliance to biocompatibility testing required for their intended use.

Sterilization:
The ProCem™ capsule components are sterilized using a gamma radiation method to assure a sterilization assurance level (SAL) of 10^{-6}. The ProCem™ device is packaged in the same manner as the predicate devices to assure sterility over their labeled shelf life.

Performance Bench Testing:
Design verification testing, including exothermic reaction, working time, snap set time, and simulated preparation properties, was successfully performed on ProCem™ to demonstrate that physical and functional requirements were met and were comparable to SerenoCem.

Conclusion:
Based upon the extensive testing conducted and the comparison to the predicate devices, it is the conclusion of Ototronix that ProCem™ is substantially equivalent to the predicate devices already on the market cleared by the 510(k) review process and presents no new concerns about safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 19, 2014

Ototronix, LLC
c/o Mr. Bernard Horwath
Regulatory Consultant
4486 Timberline Ct.
Sr. Paul, MN 55127

Re: K140644
Trade/Device Name: ProCem
Regulation Number: 21 CFR 872.3275
Regulation Name: Ear, Nose and Throat Cement
Regulatory Class: Class II
Product Code: NEA
Dated: March 12, 2014
Received: March 22, 2014

Dear Mr. Horwath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140644

Device Name
ProCem™ Otologic Bone Cement

Indications for Use *(Describe)*
ProCem™ is intended for non-weight bearing applications in Otologic surgery, such as:
1. Reconstruction of ossicular bones or mechanical coupling of the ossicular chain.
2. Mechanical stabilization of middle ear and cochlear implants.
3. Attachment of middle ear implants to the ossicular bones.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce C. Lin -S
2014.06.19 12:25:25 -04'00'

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